

II. REMARKS

Claims 18 to 24 and 48 to 70 are pending. Claims 19, 20, 51 to 54, and 56 to 59 have been withdrawn pursuant to the species election. It is noted that the Office Action Summary inadvertently includes claim 55 among the "withdrawn" claims (Paragraph 4.1).

A. Regarding the Amendments

The specification has been amended at Paragraph 1 to more clearly indicate the status of the previously filed applications to which the present application claims priority. As such, the amendment addresses a formality and does not add new matter.

The specification also has been amended at Paragraph 64 to correct a typographical error in which the name of the vector was spelled incorrectly, and at various places to more properly designate the trademarked products in order to preserve proprietary rights. As such, the amendments merely address formalities, and do not add new matter.

The specification also has been amended at Paragraph 88, to correct the reference to the provider of the recited FastTracTM kit, and to include the proper designation to the trademarked product. Relevant sections of the InvitrogenTM Corp. 1998 products catalog are submitted herewith as Exhibit A in support of the amendment to Paragraph 88. As such, no new matter has been added.

Claims 21, 23, and 48-50 have been amended to delete the term "derived". It is submitted that the amendment merely clarifies the claim language and does not add new matter.

Claim 24 has been amended to recite the terms "first cell population" and "second cell population", antecedent basis being provided by claim 18, from which claim 24 depends. As such, the amendments merely address an informality, and do not add new matter.

B. Regarding the Restriction Requirement

The species election, wherein the antibodies are IgG, IgM, IgE or IgA antibodies, is acknowledged. The Examiner has indicated that once a claim that is determined to be generic is allowed, all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim should be deemed allowable in view of the allowance of the generic claim, since the additional species will depend thereon or otherwise include all of the limitations thereof. As such, the claims withdrawn pursuant to the species election remain pending.

C. Regarding the Priority

It is stated in the Office Action that for priority under 35 U.S.C. § 119(e), the earlier filed provisional application should be referenced in the subject application. Applicants point out, however, that the application as filed contained such a reference in Paragraph 1.

It is also stated in the Office Action that the status of the parent application should be updated to indicate the abandoned status. The specification has been amended at Paragraph 1 to so update the status. As such, it is requested that this objection be withdrawn.

It is further stated in the Office Action that the priority patent applications from which the subject application claims priority were not available to the Examiner. As such, the Examiner alleges that the priority applications may not provide support for the claimed subject matter and, therefore, accorded the subject application priority only as of its October 26, 2001 filing date. The Examiner requests that Applicants identify support for the presently claimed subject matter in the parent application.

As an initial matter, Applicants point out that the subject application is stated in Paragraph 1 to be a divisional application of U.S. Serial No. 09/245,615, filed February 4, 1999. Also, in the Preliminary Amendment mailed October 26, 2001, it was stated that the subject application is substantially identical to U.S. Serial No. 09/245,615, except for the minor changes

In re Application of
Hoeffler et al.
Application No: 10/035,368
Filed: October 26, 2001
Page 12

PATENT
Attorney Docket No.: INVIT1100-2

relating to formal matters as indicated in the Amendment. As such, it is noted that the subject application should at least been accorded the February 4, 1999, filing date of U.S. Serial No. 09/245,615.

A copy of U.S. Serial No. 60/073,605, filed February 4, 1998, is attached as Exhibit B for the Examiner's consideration. Applicants submit that the pending claims are fully supported by U.S. Serial No. 60/073,605. Claim 18, is supported, for example, at page 3, line 28, to page 4, line 6; and page 22, line 23, to page 23, line 31. Claims 21-23 are supported, for example, at page 22, line 25, to page 23, line 3; and page 23, lines 13-22. Claim 24, is supported, for example, at page 21, lines 12-26. Claims 48-50, are supported, for example, at page 23, lines 13-22; and page 24, lines 23-27. Claim 55, is supported, for example, at page 6, lines 7-21. Claims 60-63, are supported, for example, at page 12, lines 11-16. Claim 64, is supported, for example, at page 11, lines 27-31; and page 12, lines 1-2. Claims 65-67, are supported, for example, at page 22, lines 11-22. Claims 68-70, are supported, for example, at page 22, lines 23-31; and page 23, lines 1-31. Accordingly, it is submitted that the pending claims are enabled by and described in U.S. Serial No. 60/073,605, February 4, 1998, and, therefore, entitled to the earliest priority.

D. Regarding the Drawings

The drawings are objected to as requiring corrections as set forth in the Draftspersons' Notice received in U.S. Serial No. 09/245,615. Formal drawings are being submitted herewith. Accordingly, it is respectfully requested that this objection be withdrawn.

E. Regarding the Information Disclosure Statement

It is stated in the Office Action that the listing of references in the specification is not a proper information disclosure statement and that a list of references to be considered must be submitted in a separate paper for consideration by the Office. Applicants acknowledge that the references cited in the specification, but not submitted in an Information Disclosure Statement (IDS), have not been considered, and submit that such references are either duplicative of information filed with an IDS in this case or not believed to be material to examination of the claimed subject matter.

F. Objection to the Specification

The specification is objected to for improperly using trademarked terms. The specification has been amended so as to properly use the trademarked terms, thus preserving the proprietary interests of the owners. Accordingly, withdrawal of the objection is respectfully requested.

The Examiner objects to the specification as allegedly improperly incorporating by reference essential material at page 7, Paragraph 29, and requests that the specification be amended to include the material incorporated by reference. This objection is traversed because the cited references describe "non-essential material" and, therefore, are properly incorporated by reference.

"Essential material" is defined as that which is necessary to 1) describe the claimed invention, 2) provide an enabling disclosure of the claimed invention, or 3) describe the best mode. Nonessential subject matter may be incorporated in the application by reference to 1) patents or applications published by the United States or foreign countries or regional patent offices, 2) prior filed, commonly owned U.S. applications, or 3) non-patent publications (see MPEP § 608.01(p)).

The material incorporated by reference at Paragraph 29 exemplifies well known methodologies for creating recombinant antibody libraries, and the skilled artisan would know of other such methods that similarly can be used. As such, the information in the cited references is nonessential because the methods are well known in the art, as indicated in the specification, and references merely describe examples of such methods. Accordingly, it is submitted that the specification need not be amended to include the material incorporated by reference because the cited material is exemplary of methods for creating a recombinant antibody library, and, therefore, respectfully request that this objection be withdrawn.

E. Rejections under 35 U.S.C. § 112

The rejections of claims 18, 21 to 24, 48 to 50, and 60 to 70 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention are respectfully traversed.

It is stated that claims 18, 21 to 24, 48 to 50, and 60 to 70 are vague and indefinite because it is not clear how the "first cell population" relates to the "second cell population" and alleged, for example, that the populations can be unrelated, in which case it would be unclear how a comparative assessment could be made. Applicants submit, however, that, one skilled in the art reading the claims, particularly in view of the specification, would know that any two cell populations can be compared according to a method of the invention, including, for example, normal cells and abnormal cells such as cancer cells; cells from different tissues or different species; and resting cells or activated cells (see Paragraph 71, at page 18). Thus, the skilled artisan clearly would know that the first cell population and second cell population can be any two cell populations of interest, the method of the invention providing, for example, a means for comparing protein expression in the two cell populations that differ, or are believed to differ, in some respect. As such, it is respectfully requested that this ground of rejection be removed.

It is also alleged that claim 23 is indefinite because the terms "resting state" and "stimulated state" are relative terms, which renders the claim indefinite. It is stated in the Office Action that "the terms are not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not reasonably be apprised of the scope of the invention" (page 6, paragraph B). It is submitted, however, the mere fact that the terms are "relative" is not dispositive as to their clarity, particularly in the present claim 23, in which the terms are used together and are "relative" with respect to one another.

Applicants submit that, based only on the plain meaning of the terms, it would be clear to one skilled in the art, reading claim 23, that cells in a "stimulated state" are those cells exposed to a "stimulus", as compared to cells in a "resting state", which are not exposed to the stimulus. In addition, the skilled artisan would know of many examples of resting and stimulated cells, including, for example, cells in the G₀ stage of the cell cycle ("resting state") as compared to cells stimulated to enter the cell cycle ("stimulated state"); or cells such as circulating T cells ("resting state") as compared to T cells activated by exposure to a particular antigen ("stimulated state"; see, for example, Paragraph 71, at page 18); or cells in a tissue under otherwise normal conditions ("resting state") as compared to the cells following perturbation by a stimulus such as an injury ("stimulated state"). Numerous additional examples of cells in a resting state as compared to a stimulated state would be well known to the skilled artisan such that the metes and bounds of the claimed subject matter clearly would be known. As such, it is respectfully requested that this ground of rejection be removed.

It is further alleged that claims 21, 23, and 48 to 50 are vague and indefinite in reciting the term "derived". Although it is submitted that one skilled in the art clearly would understand the meaning of the term "derived" as used in the claims, particularly if read in view of the specification, the claims nevertheless have been amended to delete the term. As such, it is submitted that this ground of rejection is moot.

It also is alleged that claims 48 to 50 are vague and indefinite in reciting the term "tissue type". Applicants are uncertain as to the basis for this rejection, as the term "tissue type" is well known to the skilled artisan (see, for example, "Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples; see Appendix C, a copy of which is attached hereto as Exhibit C; also available on the world wide web at URL "rand.org/publications" - search "human tissue"). As such, it is respectfully requested that this ground of rejection be removed or, in the alternative, that the Examiner clarify the basis for the rejection or provide objective evidence to support the position that the term is indefinite to one skilled in the art reading the claim.

It is further alleged that claims 55, and 60 to 63 are indefinite for being in an improper Markush format. Applicants submit, however, that the claims are in an acceptable format and are not indefinite (see, for example, MPEP § 2173.05(h) , section entitled "OR Terminology, indicating that the term "or" is acceptable language). As such, it is respectfully requested that this ground of rejection be removed.

In view of the amendments and the above remarks, it is submitted that one skilled in the art, reading the claims, would know the metes and bounds of the claimed subject matter. Accordingly, it is respectfully requested that the rejections of the claims under 35 U.S.C. § 112, second paragraph, be removed.

F. Prior Art Rejections

The rejection of claims 18, 21, 23, 24, 48, and 60 to 62 under 35 U.S.C. §§102(a)/(e) as being anticipated by Chin et al. (U.S. Patent No. 6,197,599) is respectfully traversed.

It is stated in the Office Action that Chin et al. teach a method to detect proteins by comparing protein expression using an array of antibodies. Applicants point out, however, that

anticipation under 35 U.S.C. §102(a) requires that "the invention was known or used by others in this country, or patented...before the invention thereof by the applicant for patent", and that anticipation under 35 U.S.C. § 102(e) requires that "the invention was described in...2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent...." For the reasons set forth in Section C, above, it is submitted that the claimed invention is entitled to February 4, 1998, priority date of U.S. Serial No. 60/073,605. As such, the Chin et al. patent, which was filed July 30, 1998, and issued March 6, 2001, is not prior art under 35 U.S.C. §102 with respect to the claimed invention. Accordingly, it is respectfully requested that the rejections of the claims under 35 U.S.C. §§ 102(a)/(e) be removed.

The rejection of claims 22, 50, 63, 69, and 70 under 35 U.S.C. §103(a) as being unpatentable over Chin et al. in view of Cupo (J. Chromatog., 1991) is respectfully traversed.

The Chin et al. reference is relied on as set forth above, and Cupo is combined as teaching a two-dimensional polyacrylamide gel electrophoresis procedure to measure matrix proteins. However, for the reasons set forth above, Chin et al. is not available as a prior art reference for the presently claimed invention. In the absence of Chin et al., and because Cupo does not teach or suggest comparing protein expression using an array of antibodies, it is submitted that the claimed invention would not have been obvious to one of ordinary skill in the art. Accordingly, it is respectfully requested that the rejection of claims 22, 50, 63, 70 under 35 U.S.C. § 103(a) be removed.

The rejection of claim 68 under 35 U.S.C. § 103(a) as being unpatentable over Chin et al. in view of Cupo is respectfully traversed.

It is alleged in the Office Action that, while the modification with respect to examining an arterial endothelial cell lysate as compared to a venous endothelial cell lysate is not taught in either Chin et al. or Cupo, the modification is "a mere design choice and optimization". First,

Applicants are uncertain as to why Examiner considers use of the recited cells to be a "mere design choice and optimization" and what, other than a review of the subject application, would have made it obvious to one of ordinary skill to compare the cell types recited in claim 68. It is submitted that the mere fact that one of ordinary skill may, in general, be motivated to examine protein expression in various cell types, does not provide any support for the Examiner's position that one in the art would be motivated to compare protein expression in arterial endothelial cells with that in venous endothelial cells. As such, it is submitted that the rejection should be removed for this reason or, if the rejection is not removed, that the Examiner provide some objective indicia to support the position that one of ordinary skill would have had any motivation to compare protein expression in arterial endothelial cells with that in venous endothelial cells.

Notwithstanding the above reason for removing this rejection of claim 68, Applicants further note, for the reasons set forth above, that Chin et al. is not available as prior art, and that Cupo does not provide the teaching for which Chin et al. was cited. Since no additional reference was cited in support of the present rejection of claim 68, it is submitted that the claimed invention would not have been obvious over Cupo and, therefore, respectfully requested that the rejection of claim 68 under 35 U.S.C. § 103(a) be removed.

The rejection of claims 55, and 64-67 under 35 U.S.C. § 103(a) as being unpatentable over Chin et al. in view of Kauvar (U.S. Patent No. 5,541,070) is respectfully traversed.

Chin et al. is provided for the reasons set forth above, and Kauvar is provided as teaching methods of characterizing drugs (proteins) via antibody arrays comprising different binding affinities. As discussed above, however, Chin et al. is not available as prior art, and Kauvar does not provide the teaching missing absent Chin et al. As such, it is submitted that the invention as set forth in claims 55, and 64 to 67 would not have been obvious in view of the cited references and, therefore, respectfully requested that the rejection of these claims under 35 U.S.C. § 103(a) be removed.

In re Application of
Hoeffler et al.
Application No: 10/035,368
Filed: October 26, 2001
Page 19

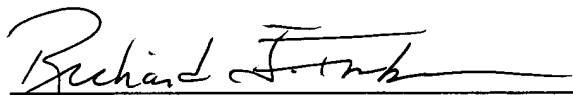
PATENT
Attorney Docket No.: INVIT1100-2

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

If any additional fee is deemed necessary in connection with the filing of the present Amendment, the Commissioner is authorized to charge (or credit) Deposit Account No. 50-1355.

Respectfully submitted,

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Attachments: Exhibit A, B and C